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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,783	12/26/2000	David R. Goodlett	P-IS 4369	3333
23601	7590	11/15/2004	EXAMINER	
CAMPBELL & FLORES LLP 4370 LA JOLLA VILLAGE DRIVE 7TH FLOOR SAN DIEGO, CA 92122			MAHATAN, CHANNING	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/748,783

Applicant(s)

GOODLETT, DAVID R.

Examiner

Channing S Mahatan

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-16,18-36 and 52-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-16,18-36 and 52-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1 Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments, filed 12 August 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-5, 7-16, 18-36 and 52-70. Claims 6, 17, and 37-51 have been cancelled.

Claims Rejected Under 35 U.S.C. § 103

The rejection of claims 1, 2, 4, 5, 12, 24, 25, 27, 33-36, 52-57, 59, 60, and 66-70 under 35 U.S.C. § 103(a) as being unpatentable over Yates (Mass Spectrometry and the Age of the Proteome, Journal of Mass Spectrometry. 1998, Volume 33, pages 1-19) are maintained for reasons of record.

Applicants' maintain the argument that Yates does not teach or suggest: 1) a method of identifying a polypeptide by simultaneously determining the mass of a subset of parent polypeptides from a population of polypeptides and the mass of fragments of the subset of parent polypeptides (claim 1); 2) a method of identifying a polypeptide where the fragment mass is determined by mass spectrometry in the absence of ion selection for producing fragment ions (claims 13, 24, and 56); and appears to support this assertion by providing the expert opinion by Dr. David R. Goodlett in the declaration under 37 C.F.R. § 1.132. Applicants' further maintain

Art Unit: 1631

Yates does not suggest or teach the use of an annotated polypeptide index, citing the context in which the term “it” (asserted to be referring to “this technique” or the peptide mass mapping by mass spectrometry rather than “databases”) is utilized in Yates. However, Applicants’ arguments are found unpersuasive.

Yates describes the use of time-of-flight mass (TOF) spectrometers to identify proteins, wherein all ions (i.e. peptide fragments) are simultaneously (fragments are separated based upon kinetic energy differences corresponding to varying fragment masses) subjected to the mass spectrometer in a field free region (i.e. absence of ion selection) (page 5, column 1, line 4 to column 2, line 21). Applicants’ have submitted the “absence of ion selection” refers to the absence of single ion selection or absence of ion selection in a source region, which can include, but does not require, selection of all polypeptides. Applicants’ then proceed to argue “...the specification does not teach, as asserted in the Office Action, that “absence of ion selection” means that all ions are fragmented at the source” and cites Figure 2B for support of this argument. However, this is not agreed with per se, wherein the specification states:

“In the absence of ion selection, instead of a single ion being selected, no selection of ions is applied but, rather, all of the ions are fragmented, leading to many peptide fragments. (page 26, lines 23-26)

Figure 2B is described in the specification as follows:

“Figure 2B shows that, instead of selecting a single parent ion, multiple parent ions (indicated in the “Source region”) are concurrently fragmented in the post-ionization region or collision cell. The fragment ions are then analyzed in a Q1 or other mass analyzer, resulting in a mass spectrum consisting of fragment ions from multiple parent ions.” (page 5, lines 16-22)

It appears Applicants’ arguments supports the Examiner’s assertion (in part); that “absence of ion selection” “can include” “selection of all ion being fragmented at the source” (i.e. field free region; selection of all ions to be fragmented at the source) which serves for the application of

Art Unit: 1631

Yates as prior art. Additionally, Figure 2B and the description of the figure makes no indication of the criteria(s)/parameter(s) for selecting fragments at the source or the number of selected fragments at the source in order for the “absence of ion selection” not to select all ions to be fragmented at the source. Further, in accordance with the disclosed description of “simultaneously determining...” (refer to previous Office Action, mailed 12 March 2004) the step of “simultaneously determining” occurs in the “absence of ion selection” when “several polypeptides can be selected rather than a single ion”, therefore “simultaneous determining” “can include” all polypeptides. Therefore, Yates describes utilizing a mass spectrometer to identify proteins wherein all ions (i.e. peptide fragments) are simultaneously subjected to the mass spectrometer in a field free region (absence of ion selection).

The context in which other types of information (i.e. database, annotated polypeptide index) is to be combined with the described technique is stated as:

“A level of uncertainty in the identification can be observed when searching large databases with this technique, consequently it has been combined with other types of information to increase the specificity of the identification.” (Paragraph bridging pages 7-8).

This has been interpreted to indicate that the technique (peptide mass mapping by mass spectrometry) when applied to “searching large databases” results in an observed “level of uncertainty in the identification”. One of skill in the art (obvious as suggested by Yates) would combine other types of information (i.e. other databases or “annotated polypeptide index”) with the technique, wherein the combination of the technique and other databases would result in the searching of these other types of information (i.e. other databases). Such combination would thereby allow for increased specificity in polypeptide identification. Yates, lists the examples of the other types of information: 1) information from proteolytic digests to increase search accuracy; 2) employing tandem mass spectrometry to sequence a peptide when an identification

Art Unit: 1631

based on a mass map is uncertain; 3) sequence information can be added to measured m/z values to increase the certainty of an identification; 4) and the information of an organism to identify similar or homologous proteins of another organism (page 8, beginning on the left column, line 10 to page 9, left column, line 5). It is again noted Applicants' "annotated polypeptide index" is disclosed as:

"An "annotated polypeptide (AP) index" refers to an index comprising at least one empirically determined characteristic for each of the polypeptides in the index, which can be determined, for example, by the methods disclosed herein." (page 19, beginning on line 28 to page 20, line 1)

With respect to the expert opinion by Dr. David R. Goodlett in the declaration under 37 C.F.R. § 1.132 this is found inadequate to overcome this rejection because there is no factual evidence supporting the statement.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to use a database (annotated polypeptide index) of predicted values and empirically determined values to improve the accuracy of polypeptide identification, since Yates discloses the combination of the technique (peptide mass mapping by mass spectrometry) and other types of information.

The rejection of claims 1-5, 12, 13-16, 23-27, 33-36, 52-60, and 66-70 under 35 U.S.C. § 103 as obvious over Yates (Mass Spectrometry and the Age of the Proteome, Journal of Mass Spectrometry. 1998, Volume 33, pages 1-19); taken in view of Gygi et al. (Quantitative analysis of complex protein mixtures using isotope-coded affinity tags, Nature Biotechnology, 17 October 1999, Volume 17, pages 994-999) are maintained for reasons of record.

Applicants' maintain the argument that the claims are unobvious over Yates, alone or in combination with Gygi et al. This is found unpersuasive.

Art Unit: 1631

Applicants are directed to the above 35 U.S.C. § 103(a) rejection which indicates that Yates teaches the used of an annotated polypeptide index (wherein it would be obvious for the index to comprise an empirically determined value) and the simultaneous determination of polypeptides using mass spectrometry in the absence of ion selection. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of quantitating the proteins identified in a single automated operation, as taught by Gygi et al. with Yates a method of identifying polypeptide(s) by mass spectrometry utilizing databases.

The rejection of claims 1-5, 7-16, 18-36, and 52-70 under 35 U.S.C. § 103 as obvious over Yates (Mass Spectrometry and the Age of the Proteome, Journal of Mass Spectrometry, 1998, Volume 33, pages 1-19); taken in view of Gygi et al. (Quantitative analysis of complex protein mixtures using isotope-coded affinity tags, Nature Biotechnology, 17 October 1999, Volume 17, pages 994-999); further in view of Easterling et al. (Routine Parts-per-Million Mass Accuracy for High-Mass Ions: Space-Charge Effects in MALDI FTICR, Analytical Chemistry, 1 February 1999, Volume 71, Number 3, pages 624-632) are maintained for reasons of record.

Applicants' maintain the argument that the above claims are unobvious over Yates, alone or in combination with Gygi et al. and/or Easterling et al. This is found unpersuasive.

Applicants are directed to the above 35 U.S.C. § 103(a) rejection which indicates that Yates teaches the used of an annotated polypeptide index (wherein it would be obvious for the index to comprise an empirically determined value) and using mass spectrometry in the absence of ion selection. Thus, it would have been obvious to one having ordinary skill in the art at the time the inventions was made to perform a wide range of mass accuracy measurements (100 ppm

Art Unit: 1631

or greater, 10 ppm or greater, etc), as taught by Easterling et al. with Yates; taken in view of Gygi et al. a method of identifying polypeptides from complex mixtures by mass spectrometry using genomic databases and quantitation of said polypeptides identified in a single automated operation.

DECLARATION UNDER 37 C.F.R. § 1.132

The declaration under 37 C.F.R. § 1.132 filed 12 August 2004 has been considered and entered. However, the declaration is insufficient to overcome the rejection of claims 1-5,7-16, 18-36 and 52-70 based upon the cited prior art of Yates (Mass Spectrometry and the Age of the Proteome, Journal of Mass Spectrometry. 1998, Volume 33, pages 1-19) taken in view of Gygi (Quantitative analysis of complex protein mixtures using isotope-coded affinity tags, Nature Biotechnology, 17 October 1999, Volume 17, pages 994-999) further in view of Easterling (Routine Parts-per-Million Mass Accuracy for High-Mass Ions: Space-Charge Effects in MALDI FTICR, Analytical Chemistry, 1 February 1999, Volume 71, Number 3, pages 624-632) as set forth in the previous Office action because:

a. the expert opinion of Dr. David R. Goodlett in the declaration under 37 C.F.R. § 1.132 is inadequate to overcome the rejection of claims 1-5,7-16, 18-36 and 52-70 based upon the cited prior art of Yates (Mass Spectrometry and the Age of the Proteome, Journal of Mass Spectrometry. 1998, Volume 33, pages 1-19) taken in view of Gygi (Quantitative analysis of complex protein mixtures using isotope-coded affinity tags, Nature Biotechnology, 17 October 1999, Volume 17, pages 994-999) further in view of Easterling (Routine Parts-per-Million Mass Accuracy for High-Mass Ions: Space-Charge Effects in MALDI FTICR, Analytical Chemistry, 1 February 1999, Volume 71, Number 3, pages 624-632) because there is no factual evidence

Art Unit: 1631

supporting the statement. That is the expert opinion by Dr. David R. Goodlett fails to set forth facts that the cited prior art does not include 1) measuring the mass of the parent polypeptides simultaneously with the mass of fragments; 2) determination of fragment mass by mass spectrometry in the absence of ion selection for producing fragment ions; as claimed in the instantly claimed method. (See M.P.E.P. 716.01(c))

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of non-obviousness fails to outweigh the evidence of obviousness. Therefore, the declaration under 37 C.F.R. § 1.132 is insufficient to overcome the rejection of claims 1-5, 7-16, 18-36 and 52-70 based upon the cited prior art of Yates taken in view of Gygi further in view of Easterling.

ACTION IS FINAL

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

EXAMINER INFORMATION

Art Unit: 1631

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Examiner Initials: *CSM*

Date: *October 28, 2004*

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11/10/04